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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,708	07/25/2003	Atsushi Suzuki	240653US0DIV	1894

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EXAMINER

HOFFMAN, SUSAN COE

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/626,708

Applicant(s)

SUZUKI ET AL.

Examiner

Susan Coe Hoffman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED, STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-9 and 20-32 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,21-23,25,26,28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,7,20,27 and 30-32 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed May 26, 2006, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 30-32 have been added.
3. Claims 6-9 and 20-32 are pending.

Election/Restrictions

4. In the reply filed on September 13, 2004, applicant elected with traverse of Group II, chlorogenic acid for species A and central nervous system stimulating components for species B. In addition, in the reply filed on June 21, 2005, applicants elected the species zingerol for the central nervous system stimulating component.

5. Regarding election of species, MPEP section 803.02 states:

... should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species.

A search of the elected species of *isolated* zingerol has revealed no prior art. However, applicant has added new claims that are not drawn to *isolated* zingerol. Prior art is applied to the new claims because zingerol is a natural component in ginger.

In the previous Office action, the search was extended to an additional species, capsaicin. This species is also examined in this Office action. Applicant has requested that all of the heat components from ginger be examined. However, the selection of the next species for

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examination is under the discretion of the examiner. Capsaicin was selected and the search will not be extended unnecessarily to cover all nonelected species.

6. Claims 8, 9, 21-23, 25, 26, 28, and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 21, 2005 and September 13, 2004.

7. Claims 6, 7, 20, 24, 27 and 30-32 are examined on the merits in regards to the elected species.

Claim Rejections - 35 USC § 112

8. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the previous Office action.

Applicant argues that the amendments to the claim renders the rejection moot because claim 6 has been amended to recite a means to determine the degree of hotness of a component. However, claim 20 still recites "heat component" without reciting a benchmark for comparison.

Claim Rejections - 35 USC § 103

9. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (The Chinese Pharm. Journal (1994), vol. 46, pp. 575-582) and the English abstract of Japanese Patent No. 63267255.

Cheng teaches using isolated chlorogenic acid to treat hypertension (see Table 1).

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JP '255 teaches using ginger to treat hypertension. Page 8 of applicant's specification states that zingerol is a component naturally found in ginger. Thus, the ginger taught by JP '255 is considered to encompass using a composition comprising zingerol to treat hypertension.

These references show that it was well known in the art at the time of the invention to use the claimed ingredients to treat hypertension. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in to treat hypertension, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating a composition for treating hypertension. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition for treating hypertension. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the

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general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Optimizing the amount of ginger would also vary the amount of zingerol. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

10. Claims 6, 7, 20, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (The Chinese Pharm. Journal (1994), vol. 46, pp. 575-582) and Suekawa et al. (Nippon yakurigaku zasshi. Folia pharmacologica Japonica (1986), vol. 88, no. 5, pp. 339-47).

Cheng teaches using isolated chlorogenic acid to treat hypertension (see Table 1).

Suekawa teaches using isolated capsaicin alone to lower blood pressure (see English abstract).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients to treat hypertension. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80;

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440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in to treat hypertension, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating a composition for treating hypertension. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition for treating hypertension. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

11. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (The Chinese Pharm. Journal (1994), vol. 46, pp. 575-582) and US Pat. No. 6,440,464 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that US '464 does not teach a composition "consisting essentially of" capsaicin to treat hypertension. However, claim 20 uses the broad claim language "comprising" rather than "consisting essentially of." Thus, the rejection of claim 20 is considered valid for the reasons of record.

Double Patenting

12. Claim 20 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No.

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09/922,694 or Application No. 10/826,289 or Appl. No 10/632,810 or Appl. No 10/810,611 or 11/106,428 in view of US Pat. No. 6,440,464 for the reasons set forth in the Office action of September 2, 2005.

Applicant has requested that this rejection be held in abeyance until allowable subject matter is indicated. For the time being, this rejection is still considered valid for the reasons of record.

13. Claims 6, 7, 20, and 27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/922,694 or Application No. 10/826,289 or Appl. No 10/632,810 or Appl. No 10/810,611 or 11/106,428 in view of Suekawa et al. (Nippon yakurigaku zasshi. Folia pharmacologica Japonica (1986), vol. 88, no. 5, pp. 339-47).

The claims of Appl. '694 or Appl. '289 or Appl. '810 or Appl. '611 or Appl. '428 all teach using chlorogenic acid to treat hypertension.

Suekawa teaches isolated capsaicin to treat hypertension (see English abstract).

As discussed above, it is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. Thus, it would be obvious to combine chlorogenic acid and capsaicin together.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections/Allowable Subject Matter

14. Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


8-2-06

Susan Coe Hoffman
Primary Examiner
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